

Remarks/Arguments:

Applicants acknowledge with appreciation the withdrawal of the previous rejections under 35 U.S.C. § 102(b) based upon U.S. Patent No. 5,594,651 to St. Ville. Applicants apologize for the inadvertent oversight of the "Interface Mechanics" rejection in the previous Office Action.

35 U.S.C. § 102 and § 103

Claims 1, 16, 31, 54 and 86 stand rejected under 35 U.S.C. § 102(b) as anticipated by "Interface Mechanics in Lower-Limb External Prosthetics: A Review of Finite Element Models" by Santosh G. Zachariah and Joen E. Sanders (hereinafter Zachariah).

Claims 1-3, 5-7, 9-10, 14, 112-113, 16-18, 20-22, 24-25, 29, 114-115, 31-37, 41, 116-117, 54, 56, 58-60, 62-63, 67-68, 118, 70, 72, 74-76, 78-79, 83-84, 86, 88-92, 96-97 and 119 stand rejected under 35 U.S.C. § 103 as unpatentable over "Balloon-Artery Interactions During Stent Placement: A Finite Element Analysis Approach to Pressure, Compliance, and Stent Design as Contributors to Vascular Injury: by Campbell Rogers, David Y. Tseng, Jaes C. Squire, and Elazer R. Edelman (hereinafter Rogers) in view of U.S. Patent No. 5,594,651 to St. Ville. Applicants respectfully traverse the rejection of these claims and respectfully submit that these claims are patentable over Zachariah, Rogers and St. Ville for at least the reasons set forth below.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. §2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

"To establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §2143. Additionally, as set forth by the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 (U.S. Apr. 30, 2007), it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed.

Independent claim 1 recites features that are neither disclosed nor suggested by any of the cited references, namely:

A system for analyzing medical devices comprising:

- a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature(s);
- a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and generates a finite element model or mesh representing both of said geometric model of said anatomical feature(s) and said geometric model of said medical device; and
- a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, load data on said anatomical feature(s) and/or said medical device and *simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device.*

Zachariah explains in the right hand column of page 289 that "external forces and displacements and internal constraints - collectively called the boundary conditions are applied at appropriate nodes within the mesh." (emphasis added). The inputs define only boundary conditions which are applied at only select nodes. The inputs do not simulate an interaction between the said anatomical features and said medical device to determine the predicted stresses, strains, and deformations of said medical device. It is respectfully submitted that Zachariah fails to teach each and every limitation of the claimed invention.

Similarly, Rogers explains in the left hand column of page 379 that "[o]ur model included input of the following: individual stent-strut width and thickness and interstrut distances of the corrugated-ring and slotted-tube stents described above, . . . The relationship of balloon-artery contact stress and contact area with the distance between 2 adjacent stent struts, balloon materials and inflation pressure was analyzed." Rogers teaches simply calculating the relationship of the contact stress and contact area of the balloon and artery. Rogers does not simulate an interaction between the said anatomical features and said medical device to determine the predicted stresses, strains, and deformations of said medical device. It is respectfully submitted that Rogers fails to teach each and every limitation of the claimed invention. The

withdrawal of the prior rejection based on St. Ville acknowledges that St. Ville does not overcome the shortcomings of Zachariah and Rogers.

For at least the foregoing reasons, Zachariah, Rogers and St. Ville, alone or in any reasonable combination, fail to disclose each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 1 is condition for allowance. Claims 2-12, 14, 15, 112 and 113 are dependent upon claim 1, and therefore, should also be allowed for the reasons urged with respect to claim 1. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 16 recites

A system for analyzing a medical device comprising:

a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of a particular individual and generates a geometric model of said anatomical feature(s);

a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and generates a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said medical device; and

a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, load data on said anatomical feature(s) and/or said medical device and *simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device.*

As discussed above in conjunction with claim 1, Zachariah, Rogers and St. Ville do not disclose or suggest a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device. For at least these reasons, Zachariah, Rogers and St. Ville fail to disclose each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 16 is condition for allowance. Claims 17-27, 29, 30, 114 and 115 are dependent upon claim 16, and therefore, should also be allowed for the reasons urged with respect to

claim 16. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 31 recites

A system for analyzing a medical device comprising:

a mesh generator that receives a geometric model of an *in vitro* anatomical feature and a geometric model of a medical device, and generates a finite element model or mesh representing both said geometric model of said *in vitro* anatomical feature and said geometric model of said medical device; and
a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said *in vitro* anatomical feature and said medical device, load data on said *in vitro* anatomical feature and/or said medical device and *simulates an interaction between said in vitro anatomical feature and said medical device to determine the predicted stresses, strains, and deformations of said medical device.*

As discussed above in conjunction with claim 1, Zachariah, Rogers and St. Ville do not disclose or suggest a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device. For at least these reasons, Zachariah, Rogers and St. Ville fail to disclose each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 31 is condition for allowance. Claims 32-39, 41, 42, 116 and 117 are dependent upon claim 31, and therefore, should also be allowed for the reasons urged with respect to claim 31. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 54 recites

A computer method for analyzing a medical device comprising:

acquiring three-dimensional volumetric data of at least one anatomical feature;
generating a geometric model of said anatomical feature(s);
receiving data representing a geometric model of a candidate medical device design;

- receiving said geometric model of said anatomical feature(s);
- generating a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device design;
- receiving material properties of said anatomical feature(s) and said candidate medical device design;
- receiving load data imposed on said candidate medical device design and said anatomical feature(s); and
- simulating an interaction between said anatomical feature(s) and said candidate medical device design to determine the predicted stresses, strains, and deformation of said candidate medical device design by said load data.*

As discussed above in conjunction with claim 1, Zachariah, Rogers and St. Ville do not disclose or suggest a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device. For at least these reasons, Zachariah, Rogers and St. Ville fail to disclose each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 54 is condition for allowance. Claims 55-65, 67-69 and 118 are dependent upon claim 54, and therefore, should also be allowed for the reasons urged with respect to claim 54. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 70 recites

- A method for analyzing a medical device comprising:
 - acquiring three-dimensional volumetric data of at least one anatomical feature of a particular individual;
 - generating a geometric model of said anatomical feature(s);
 - receiving a geometric model of a candidate medical device;
 - receiving said geometric model of said anatomical feature(s);
 - generating a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device;

receiving material properties of said anatomical feature(s) and said candidate medical device;

receiving load data imposed on said anatomical feature(s) and said candidate medical device; and

simulating an interaction between said anatomical feature(s) and said candidate medical device to determine the predicted dynamic or quasi-static stresses, strains, and deformations of said candidate medical device.

As discussed above in conjunction with claim 1, Zachariah, Rogers and St. Ville do not disclose or suggest a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device. For at least these reasons, Zachariah, Rogers and St. Ville fail to disclose each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 70 is condition for allowance. Claims 71-81 and 83-85 are dependent upon claim 70, and therefore, should also be allowed for the reasons urged with respect to claim 70. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 86 recites

A computer method for analyzing a medical device comprising:

receiving data representing a geometric model of at least one *in vitro* anatomical feature and a geometric model of a candidate medical device design; generating a finite element model or mesh representing both said geometric model of said *in vitro* anatomical feature(s) and said geometric model of said candidate medical device design;

receiving material properties of said *in vitro* anatomical feature(s) and said candidate medical device design;

receiving load data imposed on said *in vitro* anatomical feature(s) and said candidate medical device design; and

simulating an interaction between said in vitro anatomical feature(s) and said candidate medical device to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data.

As discussed above in conjunction with claim 1, Zachariah, Rogers and St. Ville do not disclose or suggest a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device. For at least these reasons, Zachariah, Rogers and St. Ville fail to disclose each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 86 is condition for allowance. Claims 87-94, 96-98 and 119-123 are dependent upon claim 86, and therefore, should also be allowed for the reasons urged with respect to claim 86. For all of these reasons, reconsideration of these claims is respectfully requested.

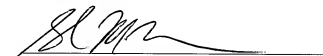
With respect to the remaining rejections under 35 U.S.C. §103, none of these cited references overcome the shortcomings of Zachariah, Rogers and St. Ville as discussed above in connection with the independent claims. Each of the dependent claims should be allowable for at least its dependence from a respective allowable independent claim.

Conclusion

In view of the points of distinction set forth above, Applicants contend that the above-identified application is in condition for allowance, which action is respectfully requested.

If the examiner believes an interview, either telephonic or in person, will advance the prosecution of this matter, it is respectfully requested that the examiner contact the undersigned to arrange the same.

Respectfully submitted,



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JLC/GMM/ap
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